DEC - 5 2000

K002782
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By:

Nuclear Diagnostics
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Sweden

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B. Device Trade Name: HERMES HDAQ Acquisition Station and HERMES Workstation
Common Name: Gamma Camera System
Classification Name: Emission Computed Tomography System

C. Predicate Devices:

GE Medical Systems	Genie Processing and Review	K964012
NUMA	NumaStation	K974444
ADAC	Image Fusion and Review System	K973233
Picker	JPACS System	K980918

D. Device Description:

The HERMES system consists of two components, a data acquisition station and a computer workstation. The HERMES HDAQ acquisition station and workstation are designed for use with commercially available gamma cameras. Software applications control acquisition, processing, display, analysis, and management of data and can be connected via network to other vendors' medical imaging workstations.

The HERMES data acquisition station receives image data from the gamma camera and interfaces with the HERMES workstation. The data acquisition station connects directly to the HERMES workstation, provides for one to three head input and up to four energy windows, and enables up to 1024 x 1024 x 32 bit acquisition. The data acquisition station can acquire data in several modes of operation: static, dynamic, gated, whole body, tomographic,

and gated tomographic. The data acquisition software performs corrections for nonuniformity, nonlinearity, and center of rotation offset.

The HERMES workstation serves as the user interface for data display, processing, analysis, and management. The workstation is a Windows-driven image processing station based on a Unix (Solaris™) operating system and standard computer hardware. The workstation is designed to process and display image data collected by the data acquisition system or transferred from other medical workstations.

HERMES software applications can display and process medical images from various modalities (e.g., SPECT, PET, CT, etc.). The software application packages are designed to store, compress (loss-less), convert, retrieve, view, search, and analyze data, including images. The applications operate as independent applications on the workstation and the acquisition station. The applications provide tools for managing data to review and quantify data. The HERMES system is capable of managing medical images as both 2-D and 3-D rendered images, including images of the heart, brain, kidneys, thyroid, and other body structures and functions. Additionally, some applications provide assessment of organ functions by computing and displaying values and providing an assessment of the data set in comparison to a reference data set.

E. Indications for Use:

The HERMES HDAQ Acquisition Station is a system designed to acquire nuclear medicine image data using a compatible gamma camera system. The HERMES Workstation is a system designed to process, display, analyze, and manage nuclear medicine and other medical imaging data transferred from other workstations or HDAQ acquisition stations.

F. Technological Comparison:

The Nuclear Diagnostics HERMES HDAQ Acquisition Station and HERMES Workstation, GE Medical Systems Genie Processing and Review, and ADAC Image Fusion and Review System have similar indications for use and overall function and perform in a similar manner with respect to data acquisition, processing, display and archiving. With regard to specific applications, the HERMES System operates similar to the Picker JPACS System (K900918) for the JaRViS and GOLD applications and to the ADAC for the multimodality package (K973233). The JaRViS module provides

access to medical images from various modalities and to clinical reports via internet or intranet using standard web-browsers on authorized workstations. The GOLD module allows short and long-term data archival of images and reports from various modalities. The operation of the HERMES acquisition station is similar to the NUMA NumaStation acquisition station.

II. Testing

Images were acquired, processed and displayed using the HERMES HDAQ Acquisition Station and HERMES Workstation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Nuclear Diagnostics AB
c/o Mr. Jim Howard
Bio-Reg Associates, Inc.
11800 Baltimore Avenue
Suite 105
BELTSVILLE MD 20705

Re: K002782
HERMES HDAQ Acquisition Station and
HERMES Workstation
Dated: August 30, 2000
Received: September 6, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Howard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002782

Device Name: HERMES HDAQ Acquisition Station and HERMES Workstation

Sponsor Name: Nuclear Diagnostics

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

David A. Eigenson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002782